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510(k) Summary

JUN - 6 2012

Submission Date:	15 May 2012
Submitter:	Spacelabs Healthcare 5150 220th Avenue SE Issaquah, WA 98029
Submitter Contact:	Spacelabs Healthcare 5150 220th Avenue SE Issaquah, WA 98029 Mr. David J. Geraghty Spacelabs Healthcare Phone: +1 (425) 657-7200, ext 5889 Fax: +1 (425) 657-7210 Email: david.geraghty@spacelabs.com
Official Contact:	Thomas Kroenke Principal Consultant Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 USA tkroenke@speedtomarket.net 303 956 4232
Manufacturing Site:	Spacelabs Healthcare 5150 220th Avenue SE Issaquah, WA 98029
Trade Name:	Spacelabs Healthcare AriaTele Telemetry Transmitter (96281)
Common and Classification Name:	Monitor, Physiological, Patient (With Arrhythmia Detection or Alarms); Electrocardiograph; Oximeter
Classification Regulation:	21 CFR §870.1025; 21 CFR §870.2340; 21 CFR §870.2700
Product Code:	MXH; DPS; DQA

Substantially Equivalent Devices:

New Spacelabs Model	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
Spacelabs Healthcare AriaTele Telemetry Transmitter (96281)	K983996	Spacelabs Medical, Inc. Spacelabs Medical Ultraview™ Digital Telemetry System

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Device Description: The Ultraview™ Digital Telemetry System (AriaTele) are portable, battery-powered, patient-worn transmitters that monitor electrocardiography (ECG) activity and oxygen saturation (SpO_2) data (96281-C only), and transmit this information to a telemetry receiver module.

There are three (3) variants of the AriaTele:

- Model 96281-A: ECG;
- Model 96281-B: ECG with display; and
- Model 96281-C: ECG and SpO_2 with display.

The AriaTele is compatible with the Ultraview SL 3800-38/-39 central monitor, and the Ultraview and Ultraview SL line of bedside monitors, collectively called "monitors." The AriaTele is also compatible with the 90478 Digital Telemetry System Receiver and Receiver Housing (90479-A, 90479-B). The receiver housing is related to the central monitor. The receiver module can go in the housing or in a bedside monitor.

The AriaTele functions as part of a digital telemetry system. The digital telemetry system consists of transmitters, diversity antennas, receiver modules, and either a receiver housing or a monitor. Typically, a request comes from a monitor to obtain data from electrodes and/or remote sensors attached to a patient which are connected to the transmitter. The monitor tells a receiver what channel to begin listening on—one that matches the transmitter on the patient.

Intended Use: The Spacelabs Healthcare AriaTele Telemetry Transmitter (96281), when used in conjunction with a Spacelabs Healthcare Ultraview patient monitor and telemetry receiver, provides a means for the continuous monitoring of electrocardiographic signals in order to detect abnormal cardiac rhythms, including life-threatening events such as high and low heart rates, asystole, and ventricular fibrillation. Optionally, on adult patients, additional abnormal cardiac rhythms, such as ventricular runs, tachycardia, and ST segment deviations are detected.

The 96281 also provides a means for both continuous and episodic monitoring of pulse blood oxygen saturation signals in order to detect desaturation caused by abnormal pulmonary/ circulatory functions.

The 96281 is intended for use with either adult or neonatal patient populations in a hospital environment.

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Technology Comparison:

The AriaTele employs the same technological characteristics as the predicate device.

Characteristic	*Predicate Device*	*Proposed Device*
Parameters	Electrocardiography (ECG); Oxygen Saturation (SpO_2) and Pulse Rate (PR); Non-invasive Blood Pressure (NIBP)	ECG; SpO_2; and PR
Accuracy of ECG Signal Reproduction	AAMI EC13	IEC 60601-2-27
SpO_2 Accuracy	Adult/Neonate: ± 3 % over 70 – 100 % Unspecified over 0 – 69 %	Adult: ± 2 % over 70 – 100 % Unspecified over 0 – 69 % Neonate: ± 3.25 % over 70 – 100 % Unspecified over 0 – 69 %
PR Accuracy	Adult/Neonate: ± 3 bpm over full range	Same.
Signal Quality Display	No	Yes
Power Source	Battery	Same

Summary of Performance Testing:

Electrical Safety

The AriaTele was tested for performance in accordance with the following Standards:

- *IEC 60601-1: 2005, Medical electrical equipment – Part 1. General requirements for basic safety and essential performance;*
- *IEC 60529: 1989, Am1: 1999, Degree of protection provided by enclosures; and*
- *UL 60601-1: 2003, Medical electrical equipment – Part 1. General requirements for safety.*

Test results indicated that the AriaTele complies with the Standards.

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Electromagnetic Compatibility (EMC) Testing

The AriaTele was tested for performance in accordance with the following Standard:

- *IEC 60601-1-2: 2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.*

Test results indicated that the AriaTele complies with the Standards.

Software Testing

Software device modifications made to the AriaTele were designed and developed according to a robust software development process, and were rigorously verified and validated.

Software information is provided in accordance with internal documentation and the following Standards and guidance documents:

- *FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05;*
- *FDA guidance: Off-the-shelf software use in medical devices, 09 Sep 99; and*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02;*

Test results indicate that the AriaTele complies with its predetermined specification and the Standards and guidance documents.

Performance Testing

The AriaTele was tested for performance in accordance with internal documentation and the following Standards:

- *IEC 60601-2-27: 2011, Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment;*
- *IEC 60601-2-49: 2011, Medical electrical equipment – Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment ;*
- *IEC 80601-2-61: 2011, Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment; and*
- *IEC 62366: 2007; Medical devices - Application of usability engineering to medical devices.*

Test results indicated that the AriaTele complies with its predetermined specification and with the applicable Standards.

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Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the software device modifications made to the AriaTele. The results of these activities demonstrate that the AriaTele is safe and effective when used in accordance with its intended use and labeling.

Therefore, the AriaTele is considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 6 2012

Spacelabs Healthcare
c/o Mr. Thomas Kroenke
Principal Consultant
Speed To Market, Inc.
P.O. Box 3018
Nederland, CO 80466

Re: K121480
Trade/Device Name: Spacelabs Healthcare AriaTele Telemetry Transmitter (96281)
Regulatory Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: MHX
Dated: May 15, 2012
Received: May 18, 2012

Dear Mr. Kroenke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121480

Indications for Use

510(k) Number (if known): K

Device Name: Spacelabs Healthcare AriaTele Telemetry Transmitter (96281)

Indications for Use:

The Spacelabs Healthcare AriaTele Telemetry Transmitter (96281), when used in conjunction with a Spacelabs Healthcare Ultraview patient monitor and telemetry receiver, provides a means for the continuous monitoring of electrocardiographic signals in order to detect abnormal cardiac rhythms, including life-threatening events such as high and low heart rates, asystole, and ventricular fibrillation. Optionally, on adult patients, additional abnormal cardiac rhythms, such as ventricular runs, tachycardia, and ST segment deviations are detected.

The 96281 also provides a means for both continuous and episodic monitoring of pulse blood oxygen saturation signals in order to detect desaturation caused by abnormal pulmonary/ circulatory functions.

The 96281 is intended for use with either adult or neonatal patient populations in a hospital environment.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121480